United States District Court
District of Massachusetts

United States of America,	)	
Plaintiff,	)	
v.	)	**Civil Action No. 20-11548-NMG**
Teva Pharmaceuticals USA, Inc., and Teva Neuroscience, Inc.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

This case arises out of an action by the United States ("the government") against Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. (collectively "Teva" or "defendants") for alleged violations of the Anti-Kickback Statute ("AKS") and the False Claims Act ("FCA"). The government alleges that defendants caused the submission of false claims to Medicare because of kickbacks Teva paid in the form of illegal copay subsidies for its multiple sclerosis drug, Copaxone.

Pending before the Court is the objection of Teva to Magistrate Judge Boal's June 7, 2022, order denying Teva's motion to compel certain Medicare claims data. Teva requests

that this Court vacate Magistrate Judge Boal's order and direct the government to respond fully to its request for production.

For the reasons that follow, Teva's objections will be overruled.

I. Background

A. Parties

Plaintiff United States, acting through the Department of Health and Human Services, administers the Health Insurance Program for the Aged and Disabled ("Medicare"). Teva is a pharmaceutical company which manufactures Copaxone, an injectable drug used to treat multiple sclerosis ("MS"), a disease of the central nervous system.

B. Fact History

From late 2006 through at least 2015, the government claims that Teva donated over $328 million to two third-party foundations, Chronic Disease Fund ("CDF") and The Assistance Fund, Inc. ("TAF"), to cover the Medicare copay obligations of Copaxone patients.

Teva administers a program known as "Shared Solutions" which provides Copaxone patients with services including educational resources, injection training and financial

assistance. Beginning in 2006, Shared Solutions referred Medicare and Medicare-eligible Copaxone patients to specialty pharmacy Advanced Care Scripts, Inc. ("ACS") to help them obtain Medicare Part D coverage and copay assistance. The government alleges that Teva worked with ACS to ensure that its donations to CDF and TAF were used solely for Copaxone copay assistance.

The government contends that Teva used CDF and TAF as conduits: it paid the foundations with the intent and understanding that they would, in turn, use the donations to cover the copays of patients taking Copaxone. Teva paid CDF and TAF tens of millions of dollars each year, the government argues, because it knew that the foundations would allocate it to cover Copaxone copays, thus increasing Copaxone sales and enriching Teva in amounts that far exceeded its payments to the foundations. CDF and TAF each operated a MS fund that covered copays for any of the many MS drugs on the market. The government maintains that Teva conspired with the foundations to use their MS funds to maximize the proportion of Copaxone patients who benefited whenever Teva made a payment to the foundations. The government submits that Teva's scheme circumvented the congressional design of the Medicare system which requires drug copays, in part, to act as a market constraint against increasing prices.

C. Procedural History

The government brought this action against defendants in August, 2020. In the complaint, it claims that Teva (1) made materially false or fraudulent claims for payment or approval to Medicare in violation of the FCA (Count I); (2) used false or fraudulent records or statements in connection with the purportedly false claims (Count II); (3) conspired with ACS, CDF and TAF to violate the FCA (Count III); and (4) was unjustly enriched as a result of sales made to Medicare patients who received copay assistance from CDF or TAF (Count IV).

In October, 2020, defendants filed a motion to dismiss. That motion was allowed in September, 2021 with respect to Count IV, but otherwise denied. Counts I, II and III remain viable against Teva.

In November, 2021, Teva served its first requests for production and interrogatories on the government. In response, the government produced all data concerning Medicare Part D Copaxone claims from January 1, 2006 to December 31, 2017, as well as the ACS, CDF and TAF disbursement data in its possession. The government states that it has produced all claims data with respect to the relevant kickback-tainted Copaxone claims in its possession.

Teva and the government conferred several times regarding Teva's request for additional data but were unable to reach a compromise and Teva then filed its motion to compel in April, 2022. In June, 2022, Magistrate Judge Boal held oral argument on the motion and promptly issued an order denying Teva's motion. Teva filed its objections to the order shortly thereafter.

II. Review of the June, 2022 Ruling by Magistrate Judge Boal

A. Legal Standard

If a party timely objects to the non-dispositive rulings of a magistrate judge on pretrial matters, the district judge must modify or set aside any part of the disputed order that is "clearly erroneous or contrary to law." Fed. R. Civ. P. 72(a); 28 U.S.C. § 636(b)(1)(A). As another session of this Court has noted,

> [a] respect for this standard is important, given the pivotal role that magistrate judges play in overseeing the conduct of the sort of complex pretrial discovery typified by this case.

Gargiulo v. Baystate Health Inc., 279 F.R.D. 62, 64 (D. Mass. 2012).

The "clearly erroneous" prong requires the district judge to accept the factual findings and conclusions of the magistrate

judge unless, after reviewing the entire record, the district judge has a "strong, unyielding belief that a mistake has been made." Green v. Cosby, 2016 WL 554816, at *1 (D. Mass. Feb. 11, 2016)(citing Phinney v. Wentworth Douglas Hosp., 199 F.3d 1, 4 (1st Cir. 1999)).

Under the "contrary to law" requirement, the district judge reviews pure questions of law de novo, see PowerShare, Inc. v. Syntel, Inc., 597 F.3d 10, 15 (1st Cir. 2010), and factual findings for clear error, Phinney, 199 F.3d at 4. Mixed questions of law and fact invoke a sliding scale of review pursuant to which

> [t]he more fact intensive the question, the more deferential the level of review (though never more deferential than the clear error standard); the more law intensive the question, the less deferential the level of review.

In re IDC Clambakes, Inc., 727 F.3d 58, 64 (1st Cir. 2013) (internal quotation marks omitted).

B. Application

1. Order on Teva's Motion to Compel Medicare Claims Data

On April 19, 2022, Teva moved to compel the production of certain Medicare claims data. It argued that these discovery requests are necessary to assess and rebut the government's

allegations, including that (1) Teva's donations allowed Teva to increase the price of Copaxone while insulating Medicare beneficiaries from price increases and (2) Teva conspired with ACS, CDF and TAF to steer Teva donations to Copaxone patients, as well as (3) whether, or to what degree, Medicare suffered any loss as a result of the alleged misconduct.

Specifically, Teva sought an order compelling the production of three categories of information for Medicare patients who received an MS diagnosis between January 1, 2006 and December 31, 2017:

1) Pharmacy Claims Data: All claims for drugs (i.e., Medicare "Part D" claims) submitted by or on behalf of Medicare patients who received a MS diagnosis during the relevant time period;

2) Medical Claims Data: All claims for medical services (i.e., Medicare "Part A," "Part B," and "Part C" claims) submitted by or on behalf of Medicare patients who received a MS diagnosis during the relevant time period, including but not limited to physician-office care, hospital care, outpatient care, skilled nursing, home health, and hospice care; and

3) Eligibility Data: All records describing the types of coverage and timeframes during which Medicare beneficiaries diagnosed with MS had Medicare coverage.

The government produced all Medicare Part D Prescription Drug Event records for Copaxone from 2006 to 2017. It also produced all disbursement data received from TAF, CDF, and ACS, including all TAF and CDF data regarding MS patients who

received copay assistance for Copaxone and other drugs and the amount of each disbursement.

In response to Teva's motion to compel, the government proclaimed that Teva's broad discovery requests likely encompass hundreds of millions of irrelevant claims for millions of patients unrelated to this case. The government contends that it would take the Centers for Medicare and Medicaid Services ("CMS") months to collect such data and that it would constitute a massive privacy intrusion upon the protected health records of Medicare patients.

After considering the arguments raised by both parties, Magistrate Judge Boal found that Teva failed to show that the requested data is relevant and she denied Teva's motion to compel on June 7, 2022. Magistrate Judge Boal found that the requested data is irrelevant to (1) Teva's price increases for Copaxone; (2) Teva's intent to induce purchases of Copaxone by Medicare patients; (3) the government's conspiracy claim; (4) any potential penalties; and (5) the calculation of damages.

2. Arguments of the Parties

Teva objects to the order of the magistrate judge, arguing that it is both clearly erroneous and contrary to law. As an initial matter, Teva contends that the discovery requests are

both proportional and relevant to damages and liability. It asserts that Magistrate Judge Boal's order is clearly erroneous because the order framed the denial on relevance grounds, rather than addressing the proportionality factors under Fed. R. Civ. P. 26(b)(1). Teva stresses that the requested data is proportional when compared to the enormous amount of penalties and damages the government seeks under the FCA in the case at bar.

Teva also objects to Magistrate Judge Boal's reliance on United States v. Rogan, 517 F.3d 449 (7th Cir. 2008) to calculate FCA damages at the full amount of the kickback-tainted claim as contrary to law, suggesting that the order prematurely decided the measure of damages. Defendants, citing United States v. Bornstein, insist that the requested data would allow Teva to develop evidence of the government's true out-of-pocket losses under a "benefit-of-the-bargain" approach to damages. See 423 U.S. 303, 316 n.13 (1976) (finding the government's damages to be equal to the difference between the market value of the product received versus the market value of the product had it been of a specified quality).

The government responds that the magistrate judge's order is correct because the principle set forth in Rogan, i.e. that

damages in an FCA case predicated on the AKS are equal to the full value of the kickback-tainted claim, is well-settled law. Furthermore, it contends that the ruling that the requested data is irrelevant to the case at bar was not clearly erroneous.

3. Review of the Magistrate Judge's Order

After a careful review of the extensive record in this case, including the transcript of the June 6, 2022, oral argument on this discovery request, this Court will affirm the disputed June, 2022 order by Magistrate Judge Boal because it is not clearly erroneous or contrary to law.

Although Magistrate Judge Boal did not explicitly analyze the proportionality factors of Fed. R. Civ. P. 26(b)(1) in her order, the record shows that both parties addressed them in their written and oral arguments. It was not clearly erroneous for the magistrate judge to conclude that production of this data is a significant burden. Nor was it contrary to law, particularly given the substantial deference due to magistrate judge rulings on heavily fact-intensive questions, for her to deny the motion on relevance grounds rather than based upon a proportionality analysis.

This Court agrees with the magistrate judge's conclusion that Teva failed to establish the relevance of the overly broad

data request to (1) Teva's intent to induce purchases of Copaxone; (2) Teva's price increases for Copaxone; (3) the government's conspiracy claim; or (4) statutory penalties under the FCA.

a. Teva's Intent to Induce Purchases of Copaxone

In its objections to the order, Teva submits that the requested data is, in fact, relevant to whether its donations induced patients to take Copaxone. It suggests that the data may demonstrate that MS patients used Copaxone because other MS therapies did not work for them, thus refuting the government's claim that Teva's donations were the motivating factor.

Teva's relevance argument fails because in an AKS-based FCA case, the government must prove only that Teva intended to induce patients to purchase Copaxone through its donations. United States v. Regeneron Pharmaceuticals, Inc., No. 20-11217, 2020 WL 7130004, at *9 (D. Mass. Dec. 4, 2020) (Saylor, C.J.) ("[I]mproperly structured donations to copay-assistance charities may violate the AKS if they are made with the intent to induce Medicare-funded referrals or drug purchases."). The requested Medicare data is irrelevant to that allegation because Teva seeks to use it for something unrelated to its own intent. Teva did not have access to the requested Medicare data at the

time so it was not clearly erroneous for the magistrate judge to find such data irrelevant to the question of intent.

b. Price Increases

Next, Teva insists that the requested discovery is relevant to the government's allegation that its scheme was motivated by a desire to increase the price of Copaxone. Teva posits that the data may show that Copaxone's price increases were due to market forces, rather than Teva's donations, if the price increases were consistent with those of other MS drugs at the time.

Teva, however, based its pricing decisions upon data available to the company at the time, not Medicare data. Thus, the requested discovery is irrelevant to any allegation of price increases and the magistrate judge's order denying the motion to compel on those grounds was not clearly erroneous.

c. Conspiracy

Teva explained at the June, 2022, hearing that it needed the pharmacy claims data to show which patients received financial assistance from CDF and TAF for non-Copaxone MS drugs ultimately reimbursed by Medicare. Teva told the magistrate judge that this "link" to Medicare would enable Teva to defend against the conspiracy theory by providing evidence of a

legitimate business affiliation in which Teva donations supported a variety of MS patients, not all of whom purchased Copaxone.

> Conspiracy liability under the FCA requires only that
>
> (1) the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States; and (2) one or more conspirators performed any act to effect the object of the conspiracy.

United States ex rel. Westmoreland v. Amgen, Inc., 738 F. Supp. 2d 267, 280 (D. Mass. 2010) (quoting United States v. President & Fellows of Harvard Coll., 323 F. Supp. 2d 151, 196 (D. Mass. 2004)). The Court is unpersuaded that evidence of whether non-Copaxone claims were reimbursed by Medicare is relevant to the conspiracy claim because it is not indicative of the existence of a conspiracy. Again, it was not clearly erroneous for the magistrate judge to hold that the pharmacy claims data is irrelevant to the conspiracy allegation.

d. FCA Penalties

Similarly, the magistrate judge found that Teva failed to articulate the relevance of the pharmacy claims data to FCA penalties. In its briefing, Teva submits that the requested data would show which claims were supported by Teva's donations and presented for Medicare reimbursement. Teva did not,

however, clarify that argument in its objections to the magistrate judge's order, which was not, therefore, clearly erroneous.

e. Damages

Finally, Magistrate Judge Boal's reference to United States v. Rogan in the context of FCA damages was not contrary to law. According to Rogan, in a FCA case predicated on the AKS, damages are equal to the full value of the kickback-tainted Medicare claim. 517 F.3d 449, 453 (7th Cir. 2008). Teva asserts, however, that it needs the requested data to calculate the government's losses and to determine damages under a "benefit of the bargain" approach.

Although the First Circuit Court of Appeals has not yet adopted the holding in Rogan, several circuit courts have accepted its approach when considering damages in AKS-tainted FCA cases. Magistrate Judge Boal correctly noted in her order that Teva did not present any "apposite authority" to Rogan to support its "benefit of the bargain" damages position. In fact, United States ex rel. Concilio De Salud Integral De Loiza, Inc. v. J.C. Remodeling, Inc., 962 F.3d 34, 43 (2020), a First Circuit case cited by Teva, discusses "FCA cases where the

entire contract price is awarded as damages." Thus, the magistrate judge's citation to Rogan was not contrary to law.

Accordingly, this Court will affirm the order of Magistrate Judge Boal entered on June 7, 2022.

ORDER

For the foregoing reasons, Teva's objections to the June 7, 2022, order of Magistrate Judge Boal (Docket No. 65) are **OVERRULED.**

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated October 11, 2022